

This listing of claims will replace all prior versions, and listings, of claims in the application:

**LISTING OF CLAIMS:**

1. **(Currently Amended)** A pharmaceutical composition comprising from about 2 mg to about 4 mg of micronized drospirenone, about 0.01 mg to about 0.05 mg of 17 $\alpha$ -ethinylestradiol, and one or more pharmaceutically acceptable carriers, the composition being in ~~an orally administrable~~ oral administration form.

2. **CANCELED**

3. **(Previously Presented)** A composition according to claim 1, wherein the amount of drospirenone is from about 2.5 mg to about 3.5 mg.

4. **(Original)** A composition according to claim 1 wherein the ethinylestradiol is in micronized form or sprayed from a solution onto particles of an inert carrier.

5. **(Previously Presented)** A composition according to claim 1, wherein the amount of ethinylestradiol is from about 0.015 mg to about 0.04 mg.

6. **(Previously Presented)** A composition according to claim 1, wherein the amount of drospirenone is from about 3.0 to about 3.5 mg and the amount of ethinylestradiol is from about 0.015 to about 0.03 mg.

7. (Currently Amended) A composition according to claim 1, wherein the pharmaceutically acceptable carrier promotes rapid dissolution of the drospirenone and 17 $\alpha$ -ethinylestradiol, the dissolution being determined by applying the USP XXIII Paddle Method using a USP dissolution test apparatus 2 at a stirring rate of 50 rpm, including 6 covered glass vessels and 6 paddles ~~paddle method~~, the dissolution media being 900 ml of water at 37°C ( $\pm 5^\circ\text{C}$ ) ~~and the stirring rate being 50 rpm~~, and wherein rapid dissolution means that at least 70% of ~~each of the~~ drospirenone and 17 $\alpha$ -ethinylestradiol are , when provided as a tablet containing 3 mg of drospirenone, is dissolved within 30 minutes.

8. CANCELED

9. (Currently Amended) A composition according to claim 7, wherein at least 80% of ~~each of the~~ drospirenone and 17 $\alpha$ -ethinylestradiol are is dissolved within 20 minutes.

10. (Currently Amended) A pharmaceutical kit comprising a number of separately packaged, individually removable, ~~and orally administrable~~ daily dosage units in oral administration form placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units each comprise a combination of micronized drospirenone in an amount of from about 2 mg to about 4 mg and 17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg.

11. **(Currently Amended)** A kit according to claim 10, which additionally comprises 7 or ~~less~~ fewer daily dosage units containing no active agent intended for oral administration subsequent to the period of at least 21 consecutive days, the total number of daily dosage units being at least 28.

12. **(Previously Presented)** A kit according to claim 11, wherein the number of daily dosage units comprising the combination of drospirenone and ethinylestradiol is 21, 22, 23 or 24, and wherein the number of daily dosage units containing no active agent is 7, 6, 5 or 4.

13. **(Previously Presented)** A kit according to claim 10, wherein the number of daily dosage units comprising the combination of drospirenone and ethinylestradiol is 28, or a multiple of 28.

14. **(Currently Amended)** A kit according to claim ~~10~~ 13, which additionally comprises a number of daily dosage units comprising the combination of drospirenone and ethinylestradiol which is a multiple of 21, 22, 23 or 24, and comprises a number of daily dosage units containing no active agent which is ~~the same~~ a multiple of 7, 6, 5 or 4.

15. **CANCELED**

16. **(Previously Presented)** A kit according to claim 10 wherein the at least 21 daily dosage units comprise drospirenone in an amount of from about 2.5 mg to about 3.5 mg and 17 $\alpha$ -ethinylestradiol in an amount of from about 0.015 mg to about 0.04 mg.

17. (Previously Presented) A kit according to claim 10, wherein the daily dosage units comprise drospirenone in an amount of from about 3.0 to about 3.5 mg and 17 $\alpha$ -ethinylestradiol in an amount of from about 0.015 to about 0.03 mg.

18. (Currently Amended) A pharmaceutical kit comprising a number of separately packaged, individually removable, ~~and orally administrable~~ daily dosage units in oral administration form placed in a packaging unit and intended for oral administration for a period of at least 28 consecutive days, wherein at least 21 of said daily dosage units comprise a combination of micronized drospirenone in an amount of from about 2 mg to about 4 mg and 17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg, wherein at least 1 but no more than 7 of said daily dosage units contain 17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg and contain no drospirenone.

19. (Previously Presented) A kit according to claim 18, wherein the number of daily dosage units comprising the combination of drospirenone and ethinylestradiol is 21, 22, 23 or 24, and wherein the number of daily dosage units comprising ethinylestradiol without drospirenone is 7, 6, 5 or 4.

20. CANCELED

21. (Previously Presented) A kit according to claim 18, wherein the at least 21 daily dosage units comprise drospirenone in an amount of from about 2.5 mg to about 3.5 mg and 17 $\alpha$ -ethinylestradiol in an amount of from about 0.015 mg to about 0.04 mg

22. (Previously Presented) A kit according to claim 18, wherein the at least 21 daily dosage units comprise drospirenone in an amount of from about 3.0 to about 3.5 mg and 17 $\alpha$ -ethinylestradiol in an amount of from about 0.015 to about 0.03 mg.

23. - 35. CANCELED

36. (Previously Presented) The composition of claim 1, wherein the drospirenone is in the form of a prodrug of the compound.

37. (Previously Presented) The composition of claim 1, wherein the 17 $\alpha$ -ethinylestradiol is in the form of an ester or ether of the compound.

38. (Currently Amended) The composition of claim 1, wherein the drospirenone is provided ~~on~~ together with a carrier which is of carboxymethylcellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, gelled starch, gelatin or polyvinylpyrrolidone.

39. (Currently Amended) The kit of claim 10, wherein the drospirenone ~~and 17 $\alpha$ -ethinylestradiol~~ are ~~is~~ provided ~~on~~ together with a carrier which is of carboxymethylcellulose,

hydroxypropyl cellulose, hydroxypropylmethyl cellulose, gelled starch, gelatin or polyvinylpyrrolidone.

40. (Currently Amended) The kit of claim 18, wherein the drospirenone and  $17\alpha$ -ethinylestradiol are is provided on together with a carrier which is of carboxymethylcellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, gelled starch, gelatin or polyvinylpyrrolidone.

41. (Previously Presented) The kit of claim 10, wherein both the drospirenone and  $17\alpha$ -ethinylestradiol are micronized.

42. (Previously Presented) The kit of claim 18, wherein both the drospirenone and  $17\alpha$ -ethinylestradiol are micronized.

43. (Previously Presented) The composition of claim 36, wherein the prodrug is an ester of drospirenone.

44. (Currently Amended) A pharmaceutical composition comprising:  
from about 2 mg to about 4 mg of drospirenone, wherein the drospirenone has a surface area of more than  $10\,000\text{ cm}^2/\text{g}$ ,  
about 0.01 mg to about 0.05 mg of  $17\alpha$ -ethinylestradiol, and  
one or more pharmaceutically acceptable carriers,

the composition being in ~~an orally administrable~~ oral administration form.

45. (Currently Amended) A pharmaceutical composition comprising:

from about 2 mg to about 4 mg of drospirenone, wherein the drospirenone is in a form, which when provided in a tablet containing 3 mg of drospirenone, has ~~having~~ a dissolution such that at least 70% of said drospirenone is dissolved ~~from a tablet containing 3 mg of drospirenone~~ in 900 ml of water at 37°C ( $\pm 5^\circ\text{C}$ ) within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 at a stirring rate of 50 rpm, including 6 covered glass vessels and 6 paddles,

about 0.01 mg to about 0.05 mg of 17 $\alpha$ -ethinylestradiol, and

one or more pharmaceutically acceptable carriers,

the composition being in ~~an orally administrable~~ oral administration form.

46. (Currently Amended) A pharmaceutical kit comprising a number of separately packaged, individually removable, ~~and orally administrable~~ daily dosage units in oral administration form placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units each comprise a combination of:

drospirenone in an amount of from about 2 mg to about 4 mg, wherein the drospirenone has a surface area of more than 10 000 ~~cm~~<sup>3</sup>/g cm<sup>2</sup>/g, and

17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg.

47. (Currently Amended) A pharmaceutical kit comprising a number of separately packaged, individually removable, ~~and orally administrable~~ daily dosage units in oral administration form placed in a packaging unit and intended for oral administration for a period of at least 21 consecutive days, wherein said daily dosage units each comprise a combination of:

drospirenone in an amount of from about 2 mg to about 4 mg, wherein the drospirenone is in a form , which when provided in a tablet containing 3 mg of drospirenone, has ~~having~~ a dissolution such that at least 70% of said drospirenone is dissolved ~~from a tablet containing 3 mg of drospirenone~~ in 900 ml of water at 37°C ( $\pm 5$  °C) within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 at a stirring rate of 50 rpm, including 6 covered glass vessels and 6 paddles, and

17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg.

48. (Currently Amended) A pharmaceutical kit comprising a number of separately packaged, individually removable, ~~and orally administrable~~ daily dosage units in oral administration form placed in a packaging unit and intended for oral administration for a period of at least 28 consecutive days,

wherein at least 21 of said daily dosage units comprise a combination of:

~~mieronized~~ drospirenone in an amount of from about 2 mg to about 4 mg, wherein the drospirenone has a surface area of more than 10 000  $\text{cm}^3/\text{g}$   $\text{cm}^2/\text{g}$ , and

17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg, and

wherein at least 1 but no more than 7 of said daily dosage units contain 17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg and contain no drospirenone.



49. (Currently Amended) A pharmaceutical kit comprising a number of separately packaged, individually removable, ~~and orally administrable~~ daily dosage units in oral administration form placed in a packaging unit and intended for oral administration for a period of at least 28 consecutive days,

wherein at least 21 of said daily dosage units comprise a combination of:

~~miconized~~ drospirenone in an amount of from about 2 mg to about 4 mg, wherein the drospirenone is in a form, which when provided in a tablet containing 3 mg of drospirenone, has a dissolution such that at least 70% of said drospirenone is dissolved ~~from a tablet containing 3 mg of drospirenone~~ in 900 ml of water at 37°C ( $\pm$  5 °C) within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 at a stirring rate of 50 rpm, including 6 covered glass vessels and 6 paddles, and

17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg, and

wherein at least 1 but no more than 7 of said daily dosage units contain 17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg and contain no drospirenone.

50. (Currently Amended) A composition or kit of claim 45, 47 or 49, wherein at least 80% of said drospirenone is dissolved within 20 minutes by the stated test.

51. (Previously Presented) A composition or kit according to claim 44, 45, 46, 47, 48 or 49, wherein the 17 $\alpha$ -ethinylestradiol is in micronized form.

52. (Currently Amended) A composition or kit according to claim 44, 45, 46, 47, ~~or 48~~ or 49, wherein the 17 $\alpha$ -ethinylestradiol ~~drospirenone~~ is sprayed from a solution onto particles of an inert carrier.

53. (Previously Presented) A composition or kit according to claim 44, 45, 46, 47, 48 or 49, wherein the amount of drospirenone is from 2.5 to 3.5 mg.

54. (Previously Presented) A composition or kit according to claim 44, 45, 46, 47, 48 or 49, wherein the amount of 17 $\alpha$ -ethinylestradiol is from 0.015 to 0.04 mg.

55. (Previously Presented) A composition or kit according to claim 44, 45, 46, 47, 48 or 49 comprising a carrier effective to promote dissolution of drospirenone and ethinylestradiol.

56. (Previously Presented) A composition or kit according to claim 55 wherein said carrier is polyvinylpyrrolidone.

57. (New) A pharmaceutical kit comprising a number of separately packaged, individually removable, daily dosage units in oral administration form in a packaging unit, including active daily dosage units which comprise a combination of micronized drospirenone in an amount of from about 2 mg to about 4 mg and 17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg, wherein the kit is adapted for administering active daily dosage units for multiple cycles of 28 consecutive days each, followed by administering the active daily dosage units for 21, 22, 23 or 24

consecutive days and subsequently administering daily dosage units containing no active agent, or administering no daily dosage units, for 7, 6, 5 or 4 consecutive days.

**58. (New)** A pharmaceutical kit comprising a number of separately packaged, individually removable, daily dosage units in oral administration form in a packaging unit, including active daily dosage units which comprise a combination of:

drospirenone in an amount of from about 2 mg to about 4 mg, wherein the drospirenone is in a form, which when provided in a tablet containing 3 mg of drospirenone, has a dissolution such that at least 70% of said drospirenone is dissolved in 900 ml of water at 37°C (+ 5 °C) within 30 minutes, as determined by USP XXIII Paddle Method using a USP dissolution test apparatus 2 at a stirring rate of 50 rpm, including 6 covered glass vessels and 6 paddles, and

17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg,

wherein the kit is adapted for administering active the daily dosage units for multiple cycles of 28 consecutive days each, followed by administering active daily dosage units for 21, 22, 23 or 24 consecutive days and subsequently administering daily dosage units containing no active agent, or administering no daily dosage units, for 7, 6, 5 or 4 consecutive days.

**59. (New)** A pharmaceutical kit comprising a number of separately packaged, individually removable, daily dosage units in oral administration form in a packaging unit, including active daily dosage units which comprise a combination of:

drospirenone in an amount of from about 2 mg to about 4 mg, wherein the drospirenone has a surface area of more than 10 000 cm<sup>2</sup>/g, and

17 $\alpha$ -ethinylestradiol in an amount from about 0.01 to about 0.05 mg,

wherein the kit is adapted for administering active daily dosage units for multiple cycles of 28 consecutive days each, followed by administering active daily dosage units for 21, 22, 23 or 24 consecutive days and subsequently administering daily dosage units containing no active agent, or administering no daily dosage units, for 7, 6, 5 or 4 consecutive days.

**60. (New)** The kit according to claim 57, 58 or 59, wherein the multiple cycles of 28 consecutive days each is 2 to 4 such cycles.

**61. (New)** A composition or kit according to claim 44, 45, 46, 47, 48, 49, 57, 58, 59 or 60 wherein the amount of drospirenone is from about 3.0 to about 3.5 mg and the amount of 17 $\alpha$ -ethinylestradiol is from about 0.015 to about 0.03 mg.

**62. (New)** A composition or kit according to claim 1, 44, 45, 46, 47, 48, 49, 57, 58, 59 or 60, wherein the amount of drospirenone is from 2.5 mg to 3.5 mg, and the amount of 17 $\alpha$ -ethinylestradiol is from 0.015 mg to 0.04 mg.

**63. (New)** A composition or kit according to claim 1, 10, 18, 44, 45, 46, 47, 48, 49, 57, 58, 59 or 60 wherein the 17 $\alpha$ -ethinylestradiol is provided in an amount of from about 0.01 to about 0.04 mg and the drospirenone is provided in a form whereby the drospirenone is exposed to the gastric environment upon dissolution.

64. (New) A composition according to claim 1, 44 or 45, wherein the composition is provided in a tablet, pill or capsule oral dosage form.

65. (New) A kit according to claim 10, 18, 46, 47, 48, 49, 57, 58, 59 or 60 wherein the daily dosage units are provided in a tablet, pill or capsule oral dosage form.

66. (New) A pharmaceutical composition comprising about 3 mg of micronized drospirenone, about 0.03 mg of micronized 17 $\alpha$ -ethinylestradiol, and one or more pharmaceutically acceptable carriers, the composition being in a tablet oral administration form.

67. (New) A pharmaceutical kit comprising a number of separately packaged, individually removable, daily dosage units in oral administration form placed in a packaging unit and intended for oral administration for a period of 28 consecutive days, wherein 21 of said daily dosage units comprise a combination of micronized drospirenone in an amount of about 3 mg and micronized 17 $\alpha$ -ethinylestradiol in an amount of about 0.03 mg, and wherein 7 of said daily dosage units contain no drospirenone or 17 $\alpha$ -ethinylestradiol.

68. (New) The composition of claim 36, wherein the prodrug is an ester of drospirenone.

69. (New) A kit according to claim 13, which additionally comprises daily dosage units comprising the combination of drospirenone and ethinylestradiol for 21, 22, 23 or 24 consecutive days and subsequent daily dosage units containing no active agent for 7, 6, 5 or 4

**Appl. No.: 09/654,227**

**December 4, 2003**

**Reply to Office Action dated June 4, 2003**

**Page 16**

consecutive days.